**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

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| ARBOR PHARMACEUTICALS, LLC,<br><br>Plaintiff,<br>v.<br>ANI PHARMACEUTICALS, INC.,<br><br>Defendant. | )<br>)<br>)<br>)<br>)<br>)<br>) | Case No. 0:17-cv-04910 (DWF-LIB)<br><br>**PLAINTIFF'S STATEMENT OF THE CASE** |

Plaintiff Arbor Pharmaceuticals, LLC ("Arbor") respectfully submits its Statement of the Case pursuant to this Court's Pretrial Conference Notice and Order [Dkt. 29].

## I. INTRODUCTION

Arbor and Defendant ANI Pharmaceuticals, Inc. ("ANI") compete in the field of prescription pharmaceuticals. Arbor markets EryPed® and E.E.S.® Granules ("EryPed and E.E.S."), the only erythromycin ethylsuccinate oral suspension antibiotic approved by the U.S. Food and Drug Administration ("FDA"). In September 2016, ANI launched its own erythromycin ethylsuccinate oral suspension (the "ANI Product") in competition with EryPed and E.E.S. To convince pharmaceutical wholesalers to purchase, and pharmacies to dispense, the ANI Product in lieu of EryPed and E.E.S., ANI falsely advertises it as an **FDA-approved**, **AB-rated**, **generic equivalent substitute** to Arbor's EryPed and E.E.S. Because the ANI Product is none of those things, ANI's advertising claims are literally false, and are actionable under the Lanham Act.

## II. LEGAL STANDARDS

Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), gives rise to a private cause of action against "[a]ny person who," in connection with any goods or services, uses in

commerce "any word" or "misleading description of fact" which "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities[.]" 15 U.S.C. § 1125(a)(1)(B). A false advertising claim's elements include:

> (1) the defendant made a false statement of fact in a commercial advertisement about its own or another's product;
>
> (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience;
>
> (3) the deception is material;
>
> (4) the defendant caused its false statement to enter into interstate commerce; and
>
> (5) plaintiff has been or is likely to be injured as a result of the false statement.

*Solvay Pharm., Inc. v. Global Pharm.*, 419 F. Supp. 2d 1133, 1143 (D. Minn. 2006).[1] A "false statement of fact" may be either "literally false as a factual matter," or "literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers." *Id.* "Proof of literally false advertising entitles a plaintiff to a presumption of actual consumer deception and the fact of harm." *Id.* at 1144.

[1] Arbor also asserts claims for unfair competition under the Lanham Act and common law, Compl. ¶¶ 51-62, and violations of the Minnesota Unfair Trade Practices Act, Uniform Deceptive Trade Practices Act, and False Advertising Act, Minn. Stat. §§ 325D.13, 325D.44, & 325F.67. Compl. ¶¶ 63-83. The core facts underlying Arbor's Lanham Act false advertising claim generally inform these other claims as well.

## III. STATEMENT OF FACTS

### A. ANI Falsely Advertises Its Product as a "Generic" to EryPed and E.E.S.

In marketing the ANI Product, ANI relies upon generic substitution for sales. Doctors write prescriptions for EryPed, the Reference Listed Drug ("RLD"), rather than for the ANI Product. Compl. ¶¶ 12, 14, 19. A pharmacist presented with a doctor's prescription for a drug product may fill the prescription by dispensing that named product or by substituting a therapeutically equivalent, "generic" version of the drug. *Id.* ¶ 20. Pharmacists and others in the pharmaceutical supply chain understand that a prescription drug described as a "generic" means that the FDA has determined that the drug is therapeutically equivalent and AB-rated to the RLD. ANI's advertising convinces drug wholesalers and retailers to purchase and stock the ANI Product as a generic substitute in place of EryPed and E.E.S., and pharmacists to substitute the ANI Product when filling prescriptions for EryPed and E.E.S. *Id.* ¶ 21.

ANI advertises its Product as a ***generic*** version of EryPed® and E.E.S.® *Id.* ¶ 18. Within the pharmaceutical industry, a "generic" drug means one that is therapeutically equivalent to the brand product prescribed. *Axcan Scandipharm, Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1074-75 & nn. 8 & 9 (D. Minn. 2007). To establish therapeutic equivalence, a drug company must have evidence that the generic product is both pharmaceutically equivalent (has the identical active ingredients, strength, route of administration, and dosage form), and is bioequivalent (exhibits the same rate and extent of absorption of the active ingredient) to the RLD. *Id.* Therapeutically equivalent drugs

can be substituted for each other with the full expectation that the products will produce the same clinical effect and have the same safety profile. Compl. ¶ 12.

ANI uses national drug databases like Medi-Span and First DataBank as a key marketing channel to promote its Product as a generic substitute for EryPed and E.E.S. Compl. ¶ 23. Based on labeling and other information ANI provides, the drug databases "linked" the ANI product as a purported generic to EryPed and E.E.S., communicating to database customers, including drug wholesalers, retailers, and pharmacists, that the ANI Product is equivalent to and substitutable for EryPed and E.E.S. *Id.* ¶¶ 7 & 23-25.

A claim of generic equivalence must be supported by evidence. *Healthpoint Ltd. v. Stratus Pharm. Inc.*, 273 F. Supp. 2d 769, 792 (W.D. Tex. 2001). A "completely unsubstantiated advertising claim by the defendant is per se false without additional evidence from the plaintiff to that effect." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 590 (3d Cir. 2002). Here, ANI failed to conduct studies to establish that its Product is bioequivalent to EryPed and E.E.S. Therefore, it lacks data sufficient to show that its Product is therapeutically equivalent to the RLD. Compl. ¶ 33. ANI's advertising claims that the ANI Product is a generic for EryPed and E.E.S. accordingly are completely unsubstantiated, and thus presumptively and literally false.

**B ANI Falsely Advertises Its Product as "AB Rated" to EryPed and E.E.S.**

The FDA assigns an "AB" rating to drug products it determines are therapeutically equivalent to the RLD. Compl. ¶ 13. An AB rating communicates to drug wholesalers, retailers, pharmacists, and others in the pharmaceutical supply chain that the product is a

therapeutically equivalent generic, that it may be safely substituted for the prescribed brand-name drug, and that it will provide the patient with the treatment the doctor ordered. *Id.* An AB rating supports and corroborates an advertising claim that a product is a generic equivalent substitute for a brand pharmaceutical.

ANI affirmatively advertises and promotes its Product as an AB-rated equivalent to EryPed and E.E.S. Compl. ¶ 22. It does this in part through the drug information databases, to which ANI submitted its labeling and other advertising, claiming that the ANI Product was AB rated by the FDA as equivalent to EryPed and E.E.S. *Id.* ¶ 24. This led third parties to repeat and amplify ANI's false advertising. *Id.* ¶ 25.

The ANI Product in fact is ***not*** AB rated as therapeutically equivalent to EryPed and E.E.S. Compl. ¶ 33. The FDA has not determined that ANI's Product is therapeutically equivalent to EryPed and E.E.S., and the FDA has not awarded the ANI Product an AB rating, or any ***other*** rating, in comparison to EryPed and E.E.S. *Id.* The Orange Book, the FDA's published list of "Approved Drug Products with Therapeutic Equivalence Evaluations," lists EryPed and E.E.S. as the "RLD," and nothing under "TE Code" for the ANI Product. Arbor's product is included in the FDA's "List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic."

ANI failed to conduct studies to establish that its Product is bioequivalent to EryPed and E.E.S., and it lacks data sufficient to demonstrate its Product's therapeutic equivalence to the RLD. Compl. ¶ 33. ANI's advertising claim that its Product is AB-rated is literally false.

**C. ANI Falsely Advertises Its Product as FDA Approved.**

Arbor's EryPed and E.E.S. are currently the only FDA-approved erythromycin ethylsuccinate for oral suspension drug products on the market. Compl. ¶ 14. Nevertheless, ANI advertises and promotes its products as FDA-approved. *Id.* ¶ 27. In claiming to market its Product "under approved ANDAs," *id.*, ANI has also caused third parties to again repeat and amplify ANI's false advertising message. *Id.* ¶ 28.

ANI's product is ***not*** FDA approved. While ANI acquired an Abbreviated New Drug Application ("ANDA") from another pharmaceutical company for a discontinued erythromycin ethylsuccinate product, Compl. ¶ 30, the product that discontinued ANDA covered had been made by a different manufacturer, at a different facility, using different manufacturing processes, and different quality control procedures than ANI uses. *Id.*

In approving drugs, the FDA considers not only the chemical composition of a product, but also all of the manufacturing processes used to make it. *E.g.*, 21 C.F.R. § 314.94(9). Certain changes in a drug's manufacturing process must be approved by the FDA. 21 C.F.R. § 314.70. The FDA must approve a "major" change to a product to be marketed under an ANDA ***before*** marketing it pursuant to a Prior Approval Supplement ("PAS"). *Id.*; *see also* Compl. ¶ 31. ANI did not submit a PAS to the FDA before it launched its Product in September 2016, and it did not wait for the FDA to approve its product before marketing it. By December 2016, FDA notified ANI that its application in connection with its Product was not approvable and required a PAS. Compl. ¶ 32. Despite this notice, ANI continued to market its products as an FDA approved, AB rated,

generic equivalent to EryPed and E.E.S. To date, FDA *still* has not approved the ANI Product.

In its pending motion to dismiss, ANI has incorrectly argued that Arbor's false advertising claim is that the ANI Product "cannot legally be marketed" because it is unapproved, Dkt. 16 at 9 & 10, and that "Arbor seeks a determination from this Court that ANI cannot lawfully market its drug product." *Id.* at 1. This mischaracterizes Arbor's claim. Arbor's Complaint makes clear that while ANI likely violates FDA law by selling its Product, any such violation is the FDA's concern. *This* suit is concerned with the false advertising ANI uses to sell that product. Compl. at 10, n.2.

## IV. DAMAGES

In a Lanham Act false advertising case, a prevailing plaintiff, "subject to the principles of equity," is entitled "to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action." 15 U.S.C. § 1117(a); *see also Masters v. UHS of Del., Inc.*, 631 F.3d 464, 473-74 (8th Cir. 2011); *Select Comfort Corp. v. Tempur Sealy Int'l, Inc.*, Case No. 13-cv-2451, 2016 WL 5496340, at *4 (D. Minn. Sept. 28, 2016) (noting: "plaintiff must only prove defendant's sales of the allegedly falsely advertised products, and defendant has the burden to prove the sales were not due to the allegedly violative conduct"). "In assessing damages the court may enter judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount." 15 U.S.C. § 1117(a); *see also Merck Eprova AG v. Brookstone Pharma., LLC*, 920 F. Supp. 404, 431

(S.D.N.Y. 2013) (trebling damages in false advertising case where defendant falsely advertising products as generic to plaintiff's products).

Arbor's ultimate recovery will be based on Arbor's own damages, ANI's profits, as well as costs, subject to the principles of equity. Because discovery will inform these calculations, it is not possible at this time to itemize the damages with further specificity.

Dated: March 19, 2018

Respectfully submitted,

*s/Andre Hanson*

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